REMARKS/ARGUMENTS

Reconsideration is requested.

Regarding the Examiner comments in paragraphs 1 to 4 of the Office Action, the reference numbers to prior patent applications and their relationships have been revised per the Examiner's suggestions in paragraph 5.

Turning to paragraph 7, Figures 9 to 19, inclusive were previously cancelled, see Amendment filed September 7, 2006 at page 124, under section heading "Amendments to the Drawings". Consequently no amendment is in order.

Paragraph 8, the sequential multiple claim dependency to which the Examiner objected has been corrected.

Paragraph 9, the steps are now identified as (a), (b), (c)..., as suggested by the Examiner.

Paragraph 11, the Examiner objects to the language "at early times after infection" as allegedly being indefinite and failing to comply with 35 U.S.C. 112, second paragraph. The Specification has extensive disclosure teaching that the NANBV capsid antigen of the claims detects the presence of NANBV antibody at an earlier time after

infection than did the previous NANBV antigens (which were not from the capsid region). Those skilled in the art will know what this means, especially upon reading the instant Specification.

The term is clearly defined in the application as filed and it is immediately evident to the skilled artisan that said term relates to an accurate detection of seroconversion at early time after acute infections.

Seroprevalence, as known in the art, refers to the number of individuals who are antibody positive for a particular infection. The appearance of such antibodies in individuals is called seroconversion.

In the experimental part, in particular beginning with Example 15 starting on page 100 of the Specification and continuing to page 108, end of first full paragraph, (which appears verbatim in applicants' Unites States Patent Application Serial No. 07/573,643 filed August 27, 1990, pages 68 to 73, included in Exhibit 2 to the Declaration of Joseph E. Mueth), it is clear to the skilled artisan what is meant by the term "at early times after infection". Here, for example, 14 weeks post-inoculation with virus is defined as "early".

As one example of the general acceptance of the term "early seroconversion", Hino (1994), Digestive Diseases and Sciences, 39:19-27 (copy attached) describes, as documented in the title, the clinical course of acute hepatitis C and changes in HCV (NANBV) markers. We would like to point, for example, to the last three lines of the abstract, where it is clearly taught that the:

> second generation anti-HCV [antibodies] was considered most useful in early diagnosis of acute plastic hepatitis C and that the anti-core titer was considered most useful in predicting prognosis of acute hepatitis C.

These post-published papers prove the inventiveness of the present patent application considering the fact that it documents the detection of early seroconversion by the use of antibodies against NANBV capsid.

Obviously, Applicant cannot provide pre-filing date of August 27, 1990 literature related to the detection of early seroconversion in HCV infection since exactly this teaching is provided in the current patent application.

Applicant is in the position to provide ample evidence for the use of the term "early" and "late" in context of seroconversion in other viral infections.

For example, the terms "early" and " late" in context of "seroconversion" was very well known in the art, and used in the field of HIV or HPV infections. In the enclosed reference Farzadegan, et al. (1989), J. Clin. Microbiol., 27:1882 (copy attached) the early seroconversion in HIV-1 infection is analyzed: see title. On page 1882, right column, second paragraph, lines 1 to 4 and lines 6 to 8 it is mentioned:

> An HIV-1 seroconverter was defined as a study participant whose serum showed new and persistent appearance, as well as progression, of bands separating antibody to P17/P24/P1/gp41/P53/P55/P64.
>
> Early infection was defined as the presence of single or faint bands to the antigens listed above on immunoblot strips with subsequent progression of antibody response.

On page 1883, right column, last two paragraphs, Farzadegan, et al. discuss, and illustrate at length, their familiarity with the concept of "early detection of seroconversion".

Similarly, the publication by Wilkins (1975) Am. J. Obstet. Gynecol., 121:908-1002 (copy attached) the late seroconversion following HPV-77, DE5 rubella virus vaccination is discussed: see title and, for example page 1000, right column, second paragraph, last line. Accordingly, the term "seroconversion" in context of "early" and

"late" was known and accepted in the virology field and was used as early as 1975.

Therefore, the term "at early times after infection" in currently pending claims is clear for the person skilled in the art and is, furthermore, unambiguously and directly derivable from the disclosure content of the application as filed.

As always, the claim language itself governs its meaning. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 [39 USPQ2d 1573] (Fed. Cir. 1996). The Federal Circuit construes the meaning of claim language according to its usage and context. ResQNet.com, Inc. v. Lansa, Inc., 346 F.3d 1374, 1378 [68 USPQ2d 1619] (Fed. Cir. 2003). The touchstone for discerning the usage of claim language is the understanding of those terms among artisans of ordinary skill in the relevant art at the time of the invention. See Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 [60 USPQ2d 1851] (Fed. Cir. 2001). Normal rules of usage create a "heavy presumption" that claim terms carry their accustomed meaning in the relevant community at the relevant time. CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 [62 USPQ2d 1658] (Fed. Cir. 2002) (citing Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 [50 USPQ2d 1607] (Fed. Cir. 1999)). Thus, the meaning of claim terms must be taken in their technological and temporal context.

The best source for discerning the proper context of claim terms is the patent specification wherein the patent applicant describes the invention. In addition to providing contemporaneous technological context for defining claim terms, the patent applicant may also explain a claim term in the specification. That is clearly the case here in regard to "at early times after infection". Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 320 F.3d 1339, 1347 [65 USPQ2d 1961] (Fed. Cir. 2003) (citing Teleflex, 299 F.3d at 1325-26). Moreover, as Federal Circuit has repeatedly counseled, the best indicator of claim meaning is its usage in context as understood by one of skill in the art at the time of invention. Ferguson Beauregard v. Mega Syst., LLC., 350 F.3d 1327, 1338 [69 USPQ2d 1001] (Fed. Cir. 2003). ("The words used in the claims must be considered in context and are examined through the viewing glass of a person skilled in the art.") Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1332 [59 USPQ2d 1401] (Fed. Cir. 2001) ("[I]t is important to bear in mind that the viewing glass through which the claims are construed is that of a person skilled in the art.") Markman v. Westview Instruments, Inc., 52 F.3d 967, 986 [34 USPQ2d 1321] (Fed. Cir. 1995) (en banc). The focus is on the objective test of what one of ordinary skill in the art at the time of the invention would have understood to mean.

35 U.S.C. § 112, second paragraph, provides: "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2 (2000). The requirement to "distinctly" claim means that the claim must have a meaning discernible

to one of ordinary skill in the art when construed according to correct principles. Union Pac. Res. Co. v. Chesapeake Energy Corp., 236 F.3d 684, 692 [57 USPQ2d 1293] (Fed. Cir. 2001) Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 1547 [221 USPQ 1] (Fed. Cir. 1984). Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must it be declaimed indefinite. Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1375 [60 USPQ2d 1272] (Fed. Cir. 2001). Only after a thorough attempt to understand the meaning of a claim has failed to resolve material ambiguities can one conclude that the claim is rejected for indefiniteness.

On the basis of well established legal principles and theory, the instant claims are not "indefinite".

This rejection under Section 112 should be withdrawn.

Turning to paragraph 12 of the Office Action, the revision of claim 112 to recite steps (a), (b) and (c) establishes the requisite antecedent for steps (b) and (c).

The rejection should be withdrawn.

Paragraph 13, the rejection on Wang, United States Patent No. 5,106,726 in view of Houghton, European Patent No. 318216 under 35 U.S.C. 103(a) as being obvious to one of ordinary skill at the time the invention was made. This rejection should be withdrawn.

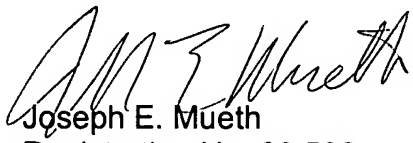
Wang issued on United States Patent Application Serial No. 558,799, filed July 26, 1990. The instant application is based on United States Patent Application Serial No. 573,643, filed August 27, 1990. Wang is not a statutory bar under Section 102. Applicants have filed herewith the Declaration Under 37 CFR 1.131 by Torsten B. Helting, a beneficial owner of the instant application, establishing that the subject matter of the instant claims was conceived in the United States and diligently pursued to a reduction to practice to establish a date of invention prior to the July 26, 1990 filing date of Wang. Consequently, the Wang patent is not "prior art".

As noted, Wang is not prior art. However, in the interest of completeness, Applicant is presently engaged in a detailed study of the Specification of the Wang patent and has preliminarily concluded that the Specification is probably inadequate as an enabling disclosure under 35 U.S.C. 112 of NANBV capsid antigen. This study is expected to be completed by the end of January 2007 at which time applicant plans to file a Supplement Response addressing the Wang patent if at all necessary.

Reconsideration and the issuance of the Notice of Allowance is requested.

Date: January 11, 2007

Respectfully submitted,



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